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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

MERTZ, PREMA MARIA

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 03/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/724,841

Applicant(s)

GRABSTEIN ET AL.

Examiner

Prema M. Mertz

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-30, 34, 35 and 41-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-30, 34-35, and 41-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicants Appeal Brief filed 1/20/2006 is acknowledged. However, upon further consideration prosecution is being re-opened by the Examiner.

Claims 20-35 and 41-45 are pending and under consideration by the Examiner.

2. The following previous objections and rejections are withdrawn in light of applicants arguments filed on 1/20/2006:

(i) the rejection of claims 20-25 under 35 USC 112, first paragraph, for recitation of new matter in claim 20; and

(ii) the rejection of claims 21-30, 34-35, 41-45 under 35 USC 112, first paragraph, lack of enablement, for the recitation of "capable of";

3. Applicant's arguments filed on 1/20/2006 have been fully considered and were persuasive in part. The issues remaining are restated below.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim rejections-35 USC § 112, first paragraph, written description rejection

5. Claims 41-45 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which has not been described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor(s) , at the time the application was filed, had possession of the claimed invention.

This rejection is maintained for reasons of record set forth at pages 3-6 of the previous Office action (8/9/2004).

Applicants argue that the written description requirement was not designed to ensure an exact match of wording between an application and claims supported in that same application; instead, it related to ensuring claim support in a previous application. Furthermore, Applicants argue that they sought to amend claim 41 to recite conditions of high stringency for hybridization as supported by the specification on page 26, line 24 but the amendment was not entered. However, contrary to Applicants arguments, Applicants are interpreting this written description rejection as a new matter rejection. The issue here is that there is no written description in the specification for claims drawn to a genus of oligonucleotides that is defined only by "...hybridizing, under conditions of moderate stringency, to a nucleic acid which encodes a polypeptide comprising SEQ ID NO:3 or 6". To provide evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics of the oligonucleotide, the specification does not provide adequate written description of the claimed genus of oligonucleotides.

With respect to the Examiner not entering the amendment of 12/8/2004, Applicants had inserted a limitation in claim 20 for 13 nucleotides drawn to SEQ ID NO:12, which is not a nucleotide but a 114 amino acid sequence. Furthermore, the 13 nucleotides inserted in claim 20 was new matter because it had not been recited in the instant application or supported in a previous application. In any case, the recitation of "high stringency" in claim 41 would not have

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obviated the written description rejection without the specific recitation in the claims of the high stringency conditions, for which there should be support and a basis for in the instant specification.

Claim rejections-35 USC § 112, second paragraph

6. Claims 20-30, 34-35, 41-45 are rejected under 35 U.S.C. 112, second paragraph.

This rejection is maintained for reasons of record set forth at page 6 of the previous Office action (8/9/2004).

Claim 20(c)-(d), lines 3-4, are rejected as vague and indefinite for the recitation of “complementary to...”, which encompasses fragments of the complement of SEQ ID NO:1 and 4 since the claim does not recite how many nucleotides there are in the complement or the length of the complement or the upper limit of the nucleotides in the complement. Furthermore, it is unclear whether the claimed nucleic acid of claim 20(c)-(d) is composed of complementary as well as non-complementary sequences of SEQ ID NO:1 or 4. In addition, this limitation encompasses any piece of nucleic acid that is the complement of SEQ ID NO:1 or 4 that is at least 12 contiguous nucleotides or 12contiguous nucleotides attached to totally unrelated nucleotides. This rejection can only be obviated by reciting “a nucleic acid which is the full complement of SEQ ID NO:1 or 4”.

Claims 21-29 are rejected as vague and indefinite because they are dependent on claim 20 which recites that the claimed nucleic acids in the Markush group of claim 20 (a)-(b) consist of the nucleic acids consisting of SEQ ID NO:1 or 4 which nucleotide sequences are 489 base pairs. It is unclear how a claimed nucleic acid, which is 489 base pairs in an independent claim, can be claimed in a dependent claim to be 12 or 14nucleotides in length.

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With respect to claims 41-45, Applicants argue that Applicants have previously sought to amend claim 41 (12/8/2004) to recite “specifically” hybridizes to the recited nucleic acid and that support for this amendment is in the specification at page 27, lines 25-29. However, contrary to Applicants arguments, page 27, lines 25-29 recites:

“Primers for the amplification of a selected sequence should be selected from sequences which are highly specific and form stable duplexes with the target sequence. The primers should also be non-complementary especially at the 3’ end, should not form dimers with themselves or other primers, and should not form secondary structures or duplexes with other regions of DNA. In general, primers of about 18 to 20 nucleotides are preferred, and may be easily synthesized using techniques well known in the art.”

Neither does the specification at page 27, lines 25-29, nor any other part of the specification recite “specifically hybridizes” and for this reason the amendment of 12/8/2004 was not entered. Furthermore, the issue here is the recitation of “moderate” which is a relative term. In the specification, page 10, lines 1-5, moderate stringency conditions have not been defined but Applicants have referred to, “for example”, the conditions in Sambrook, “which include”, “for example” overnight hybridization and post-hybridization washes at 55C, 5X SSC, 0.5% SDS. Furthermore, the relevant disclosure in Sambrook et al is “essential material” and has not been incorporated by reference. See MPEP 2163.07(b), MPEP 608.01(p) and MPEP 2181.

Claims 30, 34-35 are rejected as vague and indefinite insofar as they depend on claim 20 for its limitations.

Claim rejections-35 USC § 102

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7. Claims 20, 26, 30, 34, 35, are rejected under 35 U.S.C. 102(b) as being anticipated by Smith et al. (1991).

This rejection is maintained for reasons of record set forth at page 7 of the previous Office action (8/9/2004) and pages 4-5 of the previous Office action (3/31/2004).

Applicants argue that the oligonucleotide of Smith comprising the sequence ATGAGAATTTCGA would not specifically bind to a polynucleotide bound by the nucleic acids recited in claim 20 and would be outside the scope of the claims. Applicants also argue that Appellants therefore sought to amend claim 20 to recite “at least 14 contiguous nucleotides” and to add the proviso that the claimed nucleic acid is not ATGAGAATTTCGA. Appellants submit that this amendment, which was not entered based on the Examiner's conclusion that it is new matter (Advisory Action, December 21, 2005), does not raise an issue of new matter, because under the written description guidelines of *Capon v. Eshhar*, the claims need not re-describe what is already known. However, contrary to Applicants arguments, Applicants have provided no evidence that the identical 12 nucleotides in common in the Smith reference will not specifically bind to the complement of SEQ ID NO:1. The specific binding of the 100% identical nucleotides 1-13 of SEQ ID NO:1 and ATGAGAATTTCGA of the reference would be expected by those of skill in the art. Applicants are reminded that “Argument of counsel cannot take the place of evidence lacking in the record” (*In re Scarbrough*, 182 USPQ 298, 302 (CCPA 1974)).

According to Kennell (1971), on page 261, lines 3-6, the minimum size for a stable complex is 10 to 20 nucleotides. Claim 20 recites “specifically binding” but not “stable complex”. However, the 12 nucleotides of the reference will bind with specificity and stability

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because the 12 nucleotides of the reference are perfectly complementary to nucleotides 1-13 of SEQ ID NO:1.

The limitation “complementary to SEQ ID NO:1” in claims 20(c) encompass any piece of nucleic acid that is a complement of SEQ ID NO:1 that is at least 12 contiguous nucleotides attached to totally unrelated sequence. Applicants have recited “specific binding” for antibodies in the specification (abstract, line 3; page 24, line 1) but not defined this term for nucleic acid binding. In addition, in the absence of such a definition the term encompasses binding to 12 contiguous nucleotides of the complement of SEQ ID NO:1 specifically and anything else non-specifically.

Furthermore, Applicants are misinterpreting and misquoting the CAFC’s decision in *Capon v. Eshhar*. In *Capon* the CAFC held that the Board erred in ruling that the 35 USC § 112, first paragraph, written description requirement, imposes a per se rule requiring recitation in the specification of the nucleotide sequence for claimed DNA when that sequence is already known in the field. Contrary to Applicants arguments, in the instant case, recitation of the nucleotide sequence ATGAGAATTTCTGA in claim 20 is new matter because by adding this limitation to claim 20 Applicants were attempting to obviate a 35 USC 102(b) rejection by the Examiner. In *Capon*, Applicants did not attempt to obviate a 35 USC 102(b) rejection by adding new matter to the claims.

Therefore, the prior art anticipates claims 20, 30, 34-35.

Conclusion

No claim is allowed.

Claims 20-35, 41-45 are rejected.

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Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867.

Official papers filed by fax should be directed to (571) 273-8300. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Prema Mertz
Prema Mertz Ph.D., J.D.
Primary Examiner
Art Unit 1646
February 22, 2006